

Appendix 3: Study characteristics [posted as supplied by author]

Study Identifier and year	Country (number of sites)	N	Percent Female	Age mean (SD)	Drug	Recruitment	Baseline PSG sleep latency (subjective sleep latency)	Dosage	Design	Study quality (Max.= 22)	Study Duration (nights)	Patient type	Outcome
EFC4529 – 2004 (Zolpidem Ambien CR application number 21- 774 statistical reviews p 6)	USA(29) Canada(5) Australia (6)	212	58%	44 (13)	Zolpidem- MR or placebo	Community	Intervention: 41.7 (61.4) Placebo: 43.8 (62.0)	12.5mg	Phase II multicentre randomised double-blind placebo-controlled parallel group	16	21	Outpatients	Wake after sleep onset PSG, Sleep latency PSG, Number of awakenings PSG, Number of awakenings subjective, Sleep latency subjective, Total sleep time PSG.
EFC4530- 2004 (Zolpidem Ambien CR application number 21- 774 statistical reviews)	Argentina (5) Canada (7) France (4) Germany (6) Mexico (2) USA (16)	205	57%	70(5)	Zolpidem- MR or placebo	Community	Intervention: 36.9 (56.0) Placebo: 35.7 (62.9)	6.25 mg	Randomised multi-centre double-blind placebo-controlled	16	21	Outpatients	Wake after sleep onset PSG, Sleep latency PSG, Number of awakenings PSG, Number of awakenings subjective, Sleep latency subjective, Total sleep time PSG.
LSH17 – 1988 (Review and evaluation of clinical data, NDA 19-908 p7 (5.1.2.2.))	USA(4)	75	64%	38	Zolpidem- MR or placebo	Community	Intervention: Zolpidem 10mg: 35.8 (38.4) Zolpidem 15mg: 47.0 (61.0) Placebo: 49.9 (70.4)	10mg and 15mg	Double-blind parallel group	15	45	Outpatients	Sleep latency PSG, Sleep efficiency PSG, Number of awakenings PSG, Sleep latency subjective, Total sleep time subjective, Number of awakenings

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LSH -1992 (Review and evaluation of clinical data, NDA 19-908 p11 (5.1.2.3.))	USA (6)	145	56%	45	Zolpidem or Placebo	Community	Intervention: Zolpidem 10mg (65.1) Zolpidem 15 mg (75.9) Placebo: (58.2)	10mg and 15mg	Double-blind parallel group	15	38	Outpatients	subjective , Sleep quality subjective.
IV LSH (STILNOX STATR Statistical review and evaluation 19-908 Stilnox (zolpidem tartrate) p10)	NR	75	NR	NR	Zolpidem or Placebo	Community	Intervention: Zolpidem 10mg: 35.8 (57.0) Zolpidem 15mg : 47.0 (61.0) Placebo: 49.9 (70.4)	10mg and 15mg	Multi-centre double-blind randomised placebo controlled parallel group trial	15	35	Outpatients	Sleep latency PSG, Sleep latency subjective, Sleep efficiency PSG.
204-EU – 1997 (Sonata Stats p9)	Spain (4) France (3) Belgium (3) Netherlands (1)	130	NR	NR	Zaleplon or zolpidem or placebo	Community	Intervention: Zaleplon 10mg: 40.4 Zaleplon 20mg : 48.0 10 mg Zolpidem 10: 47.8 Placebo: 48	Zaleplon 10mg and 20mg vs zolpidem 10mg	Phase II, multicentre, double-blind comparative parallel group efficacy, safety, tolerance, outpatient and sleep laboratory trial	15	28	Outpatients	Sleep latency PSG.
Trial 301- 1998 (Sonata stats statistical review and evaluation)	USA (27)	586	58.4%	41.8	Zaleplon or zolpidem or placebo	Community	Intervention: Zaleplon 5mg: 81.5 Zaleplon 10mg: 77.7 Zaleplon 20mg: 72.5	Zaleplon 5mg, 10mg and 20mg; zolpidem 10mg	Randomised placebo controlled parallel group multicentre double-blind	16	28	Outpatients	Sleep latency PSG.

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Trial 307-1998 (Sonata stats statistical review and evaluation)*	USA and Canada (39)	637	60.6%	43	Zaleplon or Placebo	Community	Zolpidem 10mg: 70.5 Placebo: 80.4		trial				Sleep latency PSG.
Trial 303-1998 (Sonata stats statistical review and evaluation)	Europe and Canada	574	64.4%	42.8	Zaleplon or zolpidem or placebo	Community	Intervention: Zaleplon 10mg: 79.8 Zaleplon 10mg/20mg: 81.9 Placebo: 77.93	10mg/10mg, 10mg/20mg	Randomised placebo controlled parallel group multicentre double-blind trial	17	14	Outpatients	Sleep latency PSG.
Trial 306-1998 (Sonata stats statistical review and evaluation)	USA	422	64.4%	72.5	Zaleplon or Placebo	Community	Intervention: Zaleplon 5mg: 66.0 Zaleplon 10mg: 57.0 Zaleplon 20mg: 55.0 10 mg Zolpidem: 64.0 Placebo: 58.0	Zaleplon 5mg, 10mg, 20mg. Zolpidem 10mg	Randomised placebo controlled parallel group multicentre double-blind trial	17	28	NR	Sleep latency PSG.
190-049-2003 (Statistical review Estorra (Eszopiclone) NDA 21-476 p4))	USA and Canada (69)	791	63.2%	44.1	Eszopiclone or Placebo	NR	Intervention: Not given Control: Not given	5mg and 10 mg 3mg	Prospective randomized double-blind placebo-controlled five arm parallel group multi-centre trial	17	14	NR	Sleep latency PSG.
190-047-2003 (Statistical	USA (48) Canada (2)	292	65.9%	70.7	Eszopiclone or Placebo	NR	Intervention: Not given	2mg	Multicentre, randomised trial	15	14	NR	Sleep latency PSG, Sleep efficiency

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review Estorra (Eszopiclone) NDA 21-476 p5)							Control: Not given						PSG, Wake after sleep onset PSG.
190-048 - 2003 (Statistical (32)	USA and Canada	234	57.7%	72.3	Eszopiclone or Placebo	NR	Intervention: Not given	1mg and 2mg	Multicentre, randomised trial	18	14	NR	Sleep latency subjective Total sleep time subjective.
review Estorra (Eszopiclone) NDA 21- 476)							Control: Not given						

Note. N: number of participants at baseline; F: females; NR: not reported; PSG: polysomnographic.

*Trial 307-1998 had two intervention arms: (i) Zaleplon 10mg for 14 days with outcomes measured at 7 days and 14 days compared to placebo and (ii) zaleplon 10mg for 7 days followed by 20mg for 7 days with outcomes measured at 7 days and 14 days compared to placebo; in both studies we used the last measurement at 14 days and averaged the dosage at 15mg as the best approximation for the study arm using 10mg followed by 20mg zaleplon.